12/11/23

Moderna, Merck Begin Late-Stage Study for mRNA Cancer Therapy + More

The Defender's Big Pharma Watch delivers the latest headlines related to pharmaceutical companies and their products, including vaccines, drugs, and medical devices and treatments. The views expressed in the below excerpts from other news sources do not necessarily reflect the views of The Defender. Our goal is to provide readers with breaking news that affects human health and the environment.

By The Defender Staff

0

Miss a day, miss a lot. *Subscribe to The Defender's Top News of the Day.* ***It's free.***

Moderna, Merck Begin Late-Stage Study for mRNA Cancer Therapy

Reuters reported:

> Moderna (MRNA.O) and Merck & Co (MRK.N) said on Monday they have started a late-stage trial of their experimental personalized mRNA cancer treatment in combination with blockbuster drug Keytruda for patients with a type of lung cancer.
>
> The therapy, V940, belongs to a class of treatments called m-RNA-based individualized neoantigen therapy (INT) and is tailored for each patient to generate T-cells, a key part of the body's immune response, based on the specific mutational signature of a tumor.
>
> Recruitment for the study has begun globally with the first patients enrolled in Australia, the companies said.

Donate Now

You make the difference.

GUIDESTAR PLATINUM SEAL OF TRANSPARENCY 2020

Latest News

Dying to Lose Weight? U.S. Poison Control Centers Report 1,500% Spike in Calls About Popular Weight-Loss Drug

Schools, Hospitals Should Avoid Serving GMO Foods to Kids, AAP Says

Fluoride Linked to Diabetes in Kids + FDA Approves Sickle Cell Gene Therapies + More

MORE NEWS

Latest Views

Low Levels of Lead Linked to 765 Million Lost IQ Points in Kids 5 and Under

Watch: Gardasil's HPV Vaccine: Experts Weigh in on Risks, Deceptive Ad Campaigns and Lawsuits

EPA 'Safe' Limits for Pesticides on Food Geared Toward Adults, Not Kids

MORE VIEWS

Moderna and Merck started a late-stage study in July testing the combination therapy in patients with melanoma, the most deadly form of skin cancer.

Florida Official Raises Alarms About DNA in COVID Vaccines

Newsweek reported:

> Florida Surgeon General Joseph Ladapo is raising alarms about what he sees as the risk of cancer posed by COVID vaccines. Ladapo, who rose to national prominence during the pandemic for spreading misinformation about the virus and promoting vaccination hesitancy, is asking the Food and Drug Administration (FDA) and the U.S. Centers for Disease Control and Prevention (CDC) to answer questions about his concerns regarding DNA integration in mRNA vaccines.
>
> In a December 6 letter, Ladapo said he believed the drug delivery system used by mRNA vaccines could be an "efficient vehicle for delivering contaminant DNA into human cells." He said that because DNA integration could theoretically affect oncogenes — the genes that have the ability to "transform a healthy cell into a cancerous cell" — that DNA contaminant could cause cancer in vaccine recipients.
>
> On Wednesday, Ladapo pressed the FDA and CDC to answer questions about whether the risk of DNA integration was evaluated by drug manufacturers, whether FDA standards take the COVID vaccine's drug delivery system into account, and whether there is a risk of integration with reproductive cells beyond the local injection site. In a post on X (formerly Twitter), Ladapo said if FDA Commissioner Robert Califf didn't have the answers, "who gave him the right to treat human beings as guinea pigs?"
>
> "In order to affect DNA, these fragments of DNA pieces would have to integrate into DNA. That requires integration," Paul Offit, an internationally recognized infectious disease expert and the director of the Children's Hospital of Philadelphia's Vaccine Education Center, said. "Even if they got into the nucleus, they don't have a way to integrate themselves into DNA."
>
> Dan Havlichek, the chief of Michigan State's infectious disease division, told Newsweek that Ladapo's points are "legitimate," but "I doubt that we missed 18 million cases of cancer from the vaccine."

Despite New R.S.V. Shots, Most Older Adults Remain Unvaccinated

The New York Times reported:

> This winter marks the first opportunity to see how the R.S.V. vaccines work for older adults in the real world — provided those at highest risk go get vaccinated. But while cases have been climbing across the country over the past few months, only 14.8% of adults 60 and over have been vaccinated against the virus, the Centers for Disease Control and Prevention said this month.
>
> The C.D.C., citing a need for more data on potential safety concerns that arose in clinical trials, has not issued a blanket recommendation for every person 60 and older to get the shot this year. Instead, health officials have said vaccination should be targeted toward people at the highest risk of severe illness, which includes people with underlying medical conditions and those 75 and over, among others.
>
> People who get vaccinated can experience fatigue, fever and pain at the injection site. Clinical trials of the vaccines also showed a "very small but somewhat concerning" safety signal, Dr. Camille N. Kotton, an infectious disease physician at Massachusetts General Hospital and member of the C.D.C. Advisory Committee on Immunization Practices, said.
>
> Out of the roughly 38,000 older adults who received either vaccine in

Get FREE News & Updates!

First Name..

Last Name..

Email..

SIGN UP

Get Text Alerts

Sign up for breaking news from The Defender.

Currently only eligible for numbers in the U.S. and Canada.

1234567890

Phone

REQUIRED. Phone number must be in a standard 10-digit format: 1234567890 or 123-456-7890

CONTINUE

clinical trials, 20 experienced atrial fibrillation and six were reported to have developed neurological complications, including brain inflammation and a rare autoimmune condition called Guillain-Barré syndrome, in the weeks after vaccination.

"At this time, there is not enough information to determine whether these findings were simply due to chance, or if they represent an increased risk of neurologic adverse events," Dr. Michael Melgar, a medical officer with the C.D.C.'s Coronavirus and Other Respiratory Viruses Division, wrote in an email.

The Prices of 8 Drugs Were Hiked Without Proof of New Benefits, Costing the U.S. $1.2 Billion in 2022, Report Finds

STAT News reported:

During 2022, drugmakers substantially raised prices on eight widely used medicines without any new clinical evidence to justify the increases, leading patients and health insurers in the U.S. to spend an additional $1.2 billion last year, according to a new report.

The drug for which spending increased the most due to a price increase was Humira, which is used to treat rheumatoid arthritis, plaque psoriasis, and other disorders. AbbVie raised the wholesale price by 7.1%. The net price — after rebates and discounts — rose by 1.9%, most likely because the company offered more concessions than previously.

Consequently, spending for this drug climbed by $386 million, according to the report issued by the Institute for Clinical and Economic Review, a nonprofit that assesses the cost-effectiveness of medicines. The report noted that the manufacturer disputed the findings, calling the methodology "flawed" and arguing that the analysis was "subjective."

Japan Approves World's First 'Self-Amplifying' mRNA COVID Vaccine Without Published Efficacy or Safety Data

The Epoch Times reported:

Japan has approved the world's first self-amplifying mRNA (sa-mRNA) COVID-19 vaccine, although the manufacturer has not published safety or efficacy data for the shot.

Tokyo-based Meiji Seika Pharma received approval for manufacturing and marketing its Kostaive sa-mRNA COVID-19 vaccine, the company announced in a Nov. 28 press release.

The mRNA in the vaccine is designed to self-amplify when delivered into cells, which generates a "strong immune response and the potential for extended duration of protection." The vaccine is intended for primary immunization (2 doses) as well as booster immunization in adults. Kostaive is the "world's first approved product applying self-amplifying mRNA technology," according to the press release.

Both mRNA and sa-mRNA are RNA vaccines that use a virus' genetic code against it. When an mRNA vaccine is injected into an individual, the mRNA instructs cells to make a specific protein and thus stimulates immune response. A sa-mRNA vaccine takes this concept further by making multiple mRNA copies, which ends up generating more spike protein.

Toby Young, general secretary of the Free Speech Union, a public interest group, pointed out in a Nov. 30 X post that the sa-mRNA vaccine was approved in Japan "despite only testing it on 800 people, no control group and only checking antibody levels, not infection rates. Medicine regulation died with COVID."

Ozempic Side Effects Lawsuit Can Move Forward

Reuters reported:

> A Louisiana federal judge on Friday largely rejected Novo Nordisk's bid to dismiss one of the earliest lawsuits brought against the pharmaceutical company over side effects of its blockbuster drug Ozempic.
>
> U.S. District Judge James Cain Jr said plaintiff Jaclyn Bjorklund had provided enough support at this point in the case for her claim that Novo failed to warn her doctors about the risk of gastroparesis, a slowdown in the emptying of the stomach into the small intestine, associated with the drug.
>
> The judge dismissed Bjorklund's breach of express warranty claim, which accused the company of falsely marketing its drug as safe, finding she did not identify any specific promises made by Novo Nordisk. Cain dismissed the warranty claim without prejudice, meaning Bjorklund can amend her complaint and refile it.
>
> Bjorklund's lawsuit said she took Ozempic for more than a year and then switched to Mounjaro in July 2023, made by Eli Lilly, to treat her Type 2 diabetes. She said both drugs left her with severe vomiting and pain that sent her to the hospital and also caused her to lose teeth. Since Bjorklund filed her lawsuit in August, nearly 20 more have been brought against both Novo and Eli Lilly over the category of drugs, known as GLP-1 receptor agonists.

On the Streets, Opioids Sometimes More Potent Than Fentanyl: Nitazenes

The Washington Post reported:

> The novel opioids can be many times more powerful than fentanyl and can complicate overdose revivals and addiction treatment. Even as illicit fentanyl manufactured in Mexico remains by far the chief catalyst for overdose deaths in the United States, the increasing presence of nitazenes adds another layer of health concerns as users often have no inkling they are consuming those opioids.
>
> A recently unsealed federal indictment in South Florida opens a rare window into the source of nitazenes: manufacturers in China that officials say sell the drugs online and ship them to dealers in the United States. Prosecutors allege that a Deerfield Beach, Fla., man used WhatsApp and Bitcoin to purchase nitazenes to mix with fentanyl or heroin, to stretch out his supplies of opioids and make an "ultra-powerful substance."
>
> Chinese chemical and pharmaceutical companies have played a significant role in the proliferation of illicit synthetic drugs in the past decade. And although Beijing announced in November that it would curb the sale of precursor chemicals used by Mexican organized crime groups to manufacture fentanyl, experts worry that an unintended consequence could be the proliferation of other synthetic drugs such as nitazenes.
>
> Nitazenes were developed by researchers at a Swiss pharmaceutical company in the 1950s as potential painkillers but were never approved for wider use. Although they are considered opioids, the chemical structure of nitazenes differs from fentanyl and related compounds. They began appearing in the United States about 2019, after China — under pressure from the Trump administration — restricted fentanyl-related substances, which are listed as controlled substances in the United States.

Cigna Abandons Pursuit of Humana, Plans $10 Billion Share Buyback

Reuters reported:

> U.S. health insurer Cigna (CI.N) has ended its attempt to negotiate an acquisition of rival Humana (HUM.N) after the pair failed to agree on price, two sources familiar with the situation said on Sunday, as the company announced plans to buy back $10 billion worth of shares.

A Cigna-Humana combination would have created a company with a value exceeding $140 billion, based on their market values, but was certain to attract fierce antitrust scrutiny. The discussions came six years after regulators blocked mega-deals that would have consolidated the U.S. health insurance sector.

The deal talks ended due to the parties not being able to agree on price, two sources familiar with the situation said. There remains the possibility of a tie-up in the future, those sources said.

Cigna, however, on Sunday announced plans to do an additional $10 billion in share repurchases, bringing total repurchases to $11.3 billion.

Subscribe to The Defender – It's Free!

First Name.. Last Name.. Email.. SIGN UP

SUGGEST A CORRECTION

The Defender Staff

The Defender is the news and views website for Children's Health Defense. Our mission is to end corruption to save democracy. Our content exposes the corporations, elected officials, government agencies and individuals who put profits before people and planet.

Sign up for free news and updates from Children's Health Defense. CHD focuses on legal strategies to defend the health of our children and obtain justice for those injured. We can't do it without your support

Children's Health Defense Comment Policy

We welcome relevant and respectful comments. Off-topic comments may be removed.

Please read our Comment Policy before commenting.

Got it

0 Comments Login

Start the discussion...

LOG IN WITH OR SIGN UP WITH DISQUS

Name

Share Best Newest Oldest

Be the first to comment.

Subscribe Privacy Do Not Sell My Data

Children's Health Defense

Children's Health Defense® is a 501(c)(3) non-profit organization. Our mission is to end childhood health epidemics by working aggressively to eliminate harmful exposures, hold those responsible accountable and establish safeguards to prevent future harm. We fight corruption, mass surveillance and censorship that put profits before people as well as advocate for worldwide rights to health freedom and bodily autonomy.

THE DEFENDER IS AVAILABLE IN:

ENGLISH SPANISH PORTUGUESE GERMAN ITALIAN FRENCH

TAKE ACTION

DONATE FREE SIGN-UP BECOME A MEMBER

Donations are tax deductible to the full extent of the law. EIN #26-0388604

Children's Health Defense • Legal Disclaimer • Terms of Use • Privacy Policy • Donate • Work for CHD • Contact • Social • Membership FAQ

© 2016 - 2023 Children's Health Defense® • All Rights Reserved • Sitemap